PCT/EP2004/006440
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P01/7700 0.00-0309616.1

Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet from the Patent Office to help you fill in this form)

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Cardiff Road
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1. Your reference — P14899 r1/ro

2. Patent application number
(The Patent Office will fill in this part) — 28 APR 2003 — 0309616.1

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

ANGIOMED GmbH & Co.
MEDIZINTECHNIK KG
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Germany

08620981001
Patents ADP number *(if you know it)*

If the applicant is a corporate body, give the country/state of its incorporation

4. Title of the invention

LOADING AND DELIVERY OF SELF-EXPANDING STENTS

5. Name of your agent *(if you have one)*

Stephen J. Avery

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

Hoffmann Eitle
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Patents ADP number *(if you know it)*

07156466001

6. If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number

Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
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See note (d))

Yes

Patents Form 1/77

9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	0
Description	9
Claim(s)	2
Abstract	-
Drawing(s)	1 + 1

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Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	-
Request for preliminary examination and search *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	

11. I/We request the grant of a patent on the basis of this application.

Signature [signature] Date 28/04/2003

12. Name and daytime telephone number of person to contact in the United Kingdom: Stephen J. Avery, Hoffmann Eitle, 020 7404 0116

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Loading and delivery of self-expanding stents

This invention relates in one aspect to a method of loading a self-expanding stent into a delivery sheath, in which the stent in a radially confined delivery configuration is advanced axially into the sheath for delivery to a stenting site in which the sheath is withdrawn to release the stent for radial expansion at the side. In another aspect, the invention relates to a self-expanding stent within a percutaneous transluminal delivery catheter that includes a sheath that withdraws proximally to release the stent at a stenting site, and a pusher within the sheath that retains the stent at the site during withdrawal of the sheath.

EP-A-788 332 discloses a self-expanding braided metallic stent tube and a delivery system that includes a soft annulus within the stent lumen that deforms and mechanically engages with the mesh of the stent for restraining the stent from axial movement relative to the inner catheter of the delivery system, during axial movement of a sleeve surrounding the stent. The disclosure of EP-A-596 145 is similar.

EP-A-836 447 discloses a system for delivering a self-expanding stent, in which a stopper ring on an inner catheter abuts the proximal end of the stent tube during proximal withdrawal of a sheath which surrounds the stent.

The number of metals that are biologically compatible, and available for making stents, are comparatively few. One preferred material is stainless steel. One can make stainless steel stents that are plastically deformed when they are expanded radially at the stenting site. One convenient way to expand such stents is by the balloon at the distal end of a

balloon catheter. Otherwise, one can design a stainless steel stent to expand elastically when released at a stenting site. Typically, this is achieved by proximal withdrawal of a sheath on the distal end of the delivery catheter, that withdraws proximally to release the stent progressively, starting at its distal end.

Another suitable material is the nickel titanium shape memory alloy known under the trade mark NITINOL. Such stents are typically loaded into a delivery system at a low temperature when the crystal structure of the material is martensitic, and with a memory of a radially expanded shape, characteristic of a higher temperature austenitic crystalline structure. Remarkably, the nickel titanium material is biologically compatible and the martensite/austenite transformation occurs between room temperature and body temperature.

This invention is particularly applicable to self-expanding stents, irrespective of the mechanism of resilient radial expansion at the stenting site. However, the present Applicant has particular experience with nickel titanium shape memory alloy stents and the particular embodiments described below are based on such materials.

Necessarily, the tubular envelope of a stent has apertures through its wall thickness. Thus, an uncovered or "bare" stent has a tube wall that is liquid-permeable. However, there are many occasions when a stent with a liquid-impermeable wall that is not apertured would be desirable. To meet these needs, a family of "covered" stents have been developed. Applicant has particular experience with stent tubes provided with a covering of expanded polytetrafluoroethylene (ePTFE). Typically, the stent tube is covered by luminal and abluminal covering layers of ePTFE, which are bonded to each other through the apertures in the stent tube wall.

During manufacture of stents and delivery systems, attention must be paid to sterility. Specifically, one needs procedures for loading a covered stent into a catheter delivery system that will allow sterile conditions to be maintained, or at least thereafter achieved.

Typically, to introduce a covered self-expanding stent into a catheter delivery system, a tool needs to be provided that compresses the covered stent radially inwardly, down to a diameter which is smaller than the available diameter of the lumen of the delivery system that is to receive the compressed covered stent. Clearly, any structure within the lumen of the stent that resists further inward compression is better avoided, when the objective is to compress the stent radially inwardly as much as the system will tolerate, so as to keep the outside diameter of the delivery system at its distal tip as small as possible.

However, the stent has to be maintained at the stenting site during proximal withdrawal of the surrounding sheath, for progressive release of the stent at the stenting site. If there is no structure within the lumen of the stent, then the entire stress imposed on the stent, to prevent it moving proximally with the proximally withdrawing surrounding sheath, has to be carried on the proximal end annulus of the compressed stent. Often this is not really a problem, especially when the stent is short and not particularly highly compressed radially inwardly, and especially when friction between the compressed stent and the surrounding sheath can be brought to a particularly low value.

Nevertheless, it is important for management of fatigue resistance to avoid imposing on any point of the stent tube a level of stress that is higher than the designed maximum. A stent tube made of metal is susceptible to fatigue failure, if only because it is subject to cyclic stress at the

frequency of the heartbeat of the body in which it is installed. For this reason, regulatory authorities require stringent fatigue performance standards which impose on manufacturers of stents and delivery systems an onerous burden to avoid any unforeseen stresses on the stent tube.

The state of the art contains numerous suggestions to use an element within the lumen of the stent to restrain the stent from proximal withdrawal when the surrounding sleeve is withdrawn proximally. However, these systems are of interest only for bare stents, because they rely upon mechanical interaction between surfaces on the stent pusher within the stent lumen, and boundary surfaces of apertures within the wall thickness of the stent tube.

It is an object of the present invention to load self-expanding covered stents into catheter delivery systems which offers better management of stress within the stent tube, facilitates quality control and maintenance of sterile conditions, and is applicable to a range of stent tube designs.

According to one aspect of the present invention, there is provided a method of loading a self-expanding stent into a delivery sheath, as defined in claim 1 below.

According to a second aspect of the present invention there is provided a self-expanding stent within a percutaneous transluminal delivery catheter, as defined in claim 3 below.

By distributing over the full length of the stent tube lumen the forces which necessarily have to be imposed on the stent in order to:

1. load it into a delivery sheath; and/or

2. restrain it from proximal movement during proximal withdrawal of the delivery sheath during placement of the stent at the stenting site

one can manage the distribution of stress within the stent tube so that it is distributed more or less homogeneously, rather than concentrated at one end of the stent tube. By using the covering of the stent as a link in the chain of stress distribution from the pusher to the sheath, one can further avoid any point at all within the metal stent tube which is subject to stress at a level higher than a prescribed design maximum. By their nature, stent coverings are more flexible than the stent tube itself, so have the capability to distribute stress from a point on a metallic stent pusher to an area, or volume, of the metal of the stent tube.

Furthermore, the flexibility of the stent covering is sufficient to accommodate the protrusions of the pusher, irrespective where they lie in relation to the apertures of the stent lumen. With the present invention, there is no need to align in any way the protrusions of the stent pusher with the apertures of the stent lumen. Thus, a further technical effect of the present invention is valuable simplicity and speed of operation in loading a range of different covered stent products into their corresponding delivery systems.

Yet a further advantage of the present invention is that the stent pusher needs no undercut or rebated surfaces to achieve its effect, and the pusher has an outside diameter which is smaller than the inside or luminal diameter of the stent tube. These factors give greater reassurance that, when the stent has been placed, and the pusher has to be withdrawn from the stent lumen, there will be no inadvertent or unintended snagging of surfaces of the pusher on surfaces of the covered stent, or indeed of any bodily tissue that might

impinge on the surfaces of the stent pusher after it has been withdrawn proximally out of the stent lumen.

Of particular interest in the present invention is a stent pusher with protrusions arranged helically. Such protrusions will achieve the desired pushing effect when the pusher is subject to axial stress. However, arranging the protrusions helically would allow the pusher to be withdrawn from the stent lumen, even while the stent is within the sheath of the delivery system, simply by "unscrewing" the shaft of the pusher until the helical protrusions emerge, by continued rotation of the pusher relative to the stent, out of the lumen of the stent. In this way, one can employ the stent pusher of the present invention as part of a system for loading a covered stent into a sheath, but then remove the pusher, and pass the sheath stent assembly onwards for incorporation into a delivery system which uses quite another stent pusher entirely.

For a better understanding of the present invention, and to show more clearly how the same may be carried into effect, reference will now be made to the accompanying drawing, which is an axial diametral section through the distal tip of a stent delivery system which embodies the present invention.

The drawing shows only the distal tip of the delivery system, but the remainder of the system is not part of the contribution which the present invention makes to the art and, in any event, is familiar to those skilled in this art. The basis components of a conventional delivery system for a self-expanding stent an inner catheter and an outer sheath, the purpose of the outer sheath being to confine the self-expanding stent radially, to the small radius delivery configuration, until its release at the site of stenting. The purpose of the inner catheter is to restrain the stent from proximal movement with the sheath, while the sheath is being withdrawn proximally.

Looking at the drawing, the outer sheath 10 of the delivery system has an integral tapered tip 12 which narrows down to an end ring 14 of a diameter appropriate to receive a guidewire (not shown). Confined within the sheath is a covered stent of which the structural foundation is a stent body 20 which is an apertured tube of nickel titanium shape memory alloy. The stent is covered by an outer layer 22 of ePTFE on the abluminal surface of the stent body, and a covering layer 24 of ePTFE on the luminal inner surface of the stent body 20, with the inner and outer layers 24 and 22 being fused together where they can be pressed together within the apertures 26 of the stent body.

Between the luminal and abluminal surfaces of the stent body 20 is a wall thickness of the metallic stent material annulus. This annulus lies between the luminal and abluminal major surfaces of the stent body and, in the specification, we use the terminology "envelope" to indicate the generalised surfaces of the luminal and abluminal major wall surfaces of the stent body. Thus, the outer layer 22 lies outside the abluminal envelope stent body 20, except where it protrudes into the apertures 26 for fusing with the inner layer and, likewise, the inner layer 24 lies radially within the luminal envelope of the stent body 20 except where it protrudes radially outwardly into the stent body apertures 26.

The stent body carries a ring of tantalum radiopaque markers 28 at its distal end and a second ring of radiopaque tantalum markers 30 at its proximal end. It will be appreciated that the presence of these markers may further militate against pushing structures that bear against the end surface of the stent to be deployed.

The inner catheter 40 defines a guidewire lumen 42. Conveniently, the inner catheter 40 is based on a stainless steel hypo tube. This of course endows the entire delivery

system with substantial pushability, but the hypo tube can also be made remarkably flexible for the desired trackability of the system through particularly tortuous bodily lumens. In any event, if stainless steel is not flexible enough for the distal zone of the delivery system, then it would be feasible to build the inner catheter 40 from other more flexible materials such as particular polymers.

The inner catheter has an abluminal surface 44 which carries on it a wire 46 arranged as a helix so as to provide a plurality of protrusions (at least when seen in section as in the drawing) on the abluminal surface 44. In the illustrated embodiment, the wire is of stainless steel, fixed to the stainless steel tube 40 by deposits 50 of a bonding material which could be a weld bead or a suitable adhesive.

In any event, as can be seen on the drawing, when the stent body is radially inwardly compressed down onto the inner catheter 40, the inner ePTFE layer 24 deforms to accommodate the protrusions 48, but the protrusions 48 do not reach radially outwardly as far as the luminal envelope of the stent body 20.

In use, when the illustrated distal tip zone has been brought to the site of stenting, the outer catheter 12 is carefully and progressively withdrawn proximally so that the tip stretches and slides over the outer ePTFE layer 22 of the stent, progressively releasing the stent, starting at its distal end near the markers 28.

As the stent progressively expands, the inner ePTFE layer 24 moves radially outwardly away from the protrusions 48 until, with complete withdrawal of the tip 12 proximally beyond the proximal ring of radiopaque markers 30, the stent is fully released. It will be appreciated that there is then a substantial annular gap between the lumen of the expanded stent and the envelope containing the protrusions 48,

enabling the inner catheter 40 also to be withdrawn proximally from the lumen of the stent without any snagging of the inner catheter 40 on any part of the stent.

It will be appreciated that, for loading a stent into a sheath, an analogous sequence of steps may be performed, with radially inward compression of the stent body down onto the protrusions 48 of a loading tool which has a shape in section analogous to that of the inner catheter 40. Once the stent has been so compressed, a suitable sheath can be offered up to one end of the compressed stent tube, and then the stent can be urged axially into the sheath by imposing an axial force on the line of protrusions 48 through the tube 40 on which they amounted, so that this force is transferred from the protrusions 48 to the inner layer 24 and thence to the stent body 20 and the outer layer 22, so that the entire covered stent device is urged by the protrusions 48 into the receiving sheath.

A particular advantage of the helical structure of protrusions 48 as shown in the drawing is that the pusher within the stent lumen can be removed trouble-free from the lumen of the stent even when it is in a compressed configuration within a sheath as shown in the drawing, simply by "unscrewing" the pusher from within the stent lumen.

Claims

1. A method of loading a self-expanding stent into a delivery sheath, in which the stent in a radially confined delivery configuration is advanced axially into the sheath for delivery to a stenting site in which the sheath is withdrawn to release the stent for radial expansion at the site

characterized by the steps of

i) providing said stent as a covered stent having a metal matrix with surfaces defining luminal and abluminal envelopes spaced apart by a stent wall thickness, a covering material bonded to the matrix lying radially inside the luminal envelope

ii) providing a stent pusher within the lumen of the stent, when the stent has a radius greater than its radius in its delivery configuration, the stent pusher having radially outwardly extending protrusions distributed along the length of the stent lumen

iii) compressing the stent radially inwardly until the protrusions deform the covering material, yet remain radially inside the luminal envelope, and

iv) advancing the compressed stent into the sheath by imposing an endwise force on the stent pusher so that the covering material transfers the pushing force radially outwardly from the protrusions of the stent pusher to the stent matrix.

2. Method as claimed in claim 1, including the step of arranging the protrusions helically, so that the stent pusher can be withdrawn from the lumen of the stent, inside the sheath, by unscrewing the stent pusher relative to the stent lumen.

3. A self-expanding stent within a percutaneous transluminal delivery catheter that includes a sheath that withdraws proximally to release the stent at a stenting site,

and a pusher within the sheath that retains the stent at the site during withdrawal of the sheath

characterised in that

i) the pusher extends along the lumen of the stent and has radially outwardly extending protrusions distributed along the length of the stent lumen

ii) the stent is a covered stent having a metal matrix with surfaces defining luminal and abluminal envelopes spaced apart by a stent wall thickness, a covering material bonded to the matrix lying radially inside the luminal envelope; and

iii) the protrusions deform the covering material yet remain radially inside the luminal envelope.